**Remarks/Arguments:**

Claims 19-22 are pending.

Claims 1-18 are cancelled, without prejudice or disclaimer.

Applicants wish to thank the examiner for expressly indicating—in the final Office Action—withdrawal of the previous rejections of record.

Claims 19-22 were objected to for beginning with the phrase "In a method." According to the statement of objection, claims should begin with the article "A" or "The."

Beginning a claim with the article "A" or "The" is ordinarily correct. However, when the claim at issue is in Jespen format—requiring a transitional phrase such as "wherein the improvement comprises" (37 CFR 1.175(e)—beginning the claim with the article "A" or "The" would make it very difficult to effect proper sentence structure (i.e., pursuant to the rules of English grammar and syntax). Therefore, Jespen type claims traditionally begin with the words "In a". Withdrawal of the objection appears to be in order.

Claims 19-22 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Reconsideration is requested.

As readily apparent to one skilled in the art, the term "standardized" denotes that all "unit doses" have an identical composition. The reactivity of blood cells in every "standardized unit dose"— due to identical composition of the blood unit doses—is controlled , in the measurement with suitable positive and negative control materials (e.g., endotoxin reference materials).

Thus, the term "standardized," as used in the present claims, expressly recites the inherent effect provided by using multiple *aliquots* of whole blood. Using multiple aliquots of whole blood from the same donor achieves standardization automatically, as it were, as these aliquots are based on the same whole blood sample.

Claims 12-22 were rejected under 35 USC 102(b) as allegedly anticipated by each of Rubinstein and Kaye. Reconsideration is respectfully requested.

Cryopreservation of cells has been known for decades. It preserves cellular material for later studies. Rubinstein and Kaye are but two of many references that describe the cryopreservation of blood cells. However, the known methods of cryopreservation—as taught by Rubinstein and Kaye—neither teach nor suggest the presently claimed method, which results in a cryopreserved standardized cellular reagent useful, e.g., for pyrogen detection.

Each of Rubinstein and Kaye is missing the salient innovative aspect of the presently claimed invention, i.e., creating a cellular reagent for testing, which reagent is <u>standardized</u> and can be provided in <u>multiple, identical unit doses</u> (aliquots). In other words, neither reference teaches or suggests cryopreserving *standardized blood unit dose* for testing an "immunofunctional, toxic, or modulatory blood reaction," as recited in the rejected claims. As explained, above, *standardized* denotes the reactivity of the blood cells, due to identical composition of the blood units, which is controlled in the measurement with suitable positive and negative control materials (e.g., endotoxin reference materials).

Rubinstein teaches cryopreserving a single aliquot of cells for therapeutic purposes. On the other hand, the presently claimed invention involves cryopreserving identical multiple aliquots of cells, i.e., cryopreserving a "standardized" reagent, for measurement—not therapeutic—purposes. Moreover, Rubinstein's cryopreserved aliquot of cells requires further processing (removal of hypertonic protectant) before use.

Kaye teaches a method of cryopreserving a sample of whole blood in conjunction with diagnosing HIV-1 infection. DNA recovered from thawed cryoprecipitate is found effective for diagnosing HIV-1 infection by polymerase chain reaction (PCR).

Kaye does not involve testing the thawed cryopreserved cells, themselves, let alone testing the cells for a biological response, i.e., the use for which the cryopreserved "standardized" reagent—in accordance with the presently claimed invention—is intended.

More importantly, Kaye teaches only cryopreserving an entire donor blood sample as a single unit, i.e., not the multiple units (as multiple donor samples or multiple units from a single sample) constituting the "standardized"reagent, in accordance with the present, rejected claims. And, moreover, further processing is required (as in Rubinstein). Thus, as with Rubinstein, identical, ready-to-use aliquoted cellular reagents are not obtained by Kaye, in contrast to the present claims.

Each of Rubinstein and Kaye relates to the field of *therapy*, while the presently claimed invention relates to the field of *diagnosis/measurement*. Moreover, Rubinstein and Kaye both describe measuring *within* the frozen samples; whereas, according to the presently claimed invention, measuring is done *with* the frozen samples.

In other words, the whole blood units according to the presently claimed invention function as a *measuring device*—for measuring an immunofunctional, toxic, or modulatory blood reaction. As set forth in the subject application as filed (page 8, first incomplete paragraph), the presently claimed invention provides the

> testing of materials for immune-related effects such as pyrogenicity, immunomodulatory or immunotoxic effects.

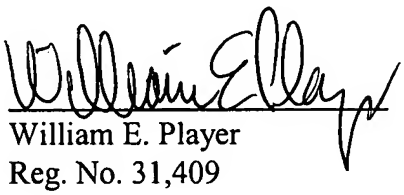
Neither Rubinstein nor Kaye provides measuring an immunofunctional, toxic, or modulatory blood reaction.

For the foregoing reasons, withdrawal of the rejections under §102(b) appears to be in order.

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By 
William E. Player
Reg. No. 31,409

400 Seventh Street, NW
The Jenifer Building
Washington, D.C. 20004
Tel. (202) 638-6666
Fax (202) 393-5350
Date: December 3, 2007
WEP/jhr
R:\Home\WPLAYE\wep&secretary\2007\December\P61750US1 afamd.wpd